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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,655	08/03/2001	Michael H. Cardone	M00925/70106	5833

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EXAMINER

CHEU, CHANGHWA J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 12/02/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/921,655

Applicant(s)

CARDONE ET AL.

Examiner

Jacob Cheu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 73 and 74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's amendment filed on September 10, 2003 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claim 11-72 are cancelled.
2. Claim 73-73 are added to the instant application.
3. Currently, claims 1-10, 73-74 are under examination.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 4, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bosslet et al. (5643731).

Bosslet et al. teach a method of using leucine zipper peptides for in vitro diagnosis. Bosslet et al. teach covalently attaching one of the pair of "leucine zipper" to the solid phase, i.e. microtiter. (Col. 3, line 57-64; Figure 1-2) The leucine zipper serves as a linker to connect an antibody covalently via maleimide group. (See example 2, particularly step 4)

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2, 5, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bosslet et al. in view of Sakata et al. (EP 0140489) and Bagchi et al.. (US 4855219)

Bosslet et al. reference has been discussed but does not explicitly teach using linker comprising vinyl sulfone, carboxy, succinimide and hydroxy succinimide groups. Sakata et al. teach using covalent modification for immunodetection, such as adding hydroxyl, carboxyl, succinimide or sulfhydryl groups. (page 5, line 18-22; 6, line 5 to page 7, line 1-15) Bagchi et al. also teach using compounds containing vinyl sulfone groups for cross-linking purposes on the solid support, i.e. microplate (Col. 3, line 12-18) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Bosslet et al. with the methods of covalent attachment of microplate with carriers as taught by Sakata and Bagchi et al, since covalent modification on a solid phase in increasing sensitivity of immunoassay is well-known in the art.

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7. Claims 9-10 and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bosslet et al. in view of MacBeath et al. (J. Am. Chem. Soc. 1999 121: 7967-7968)

Bosslet et al. reference has been discussed but does not explicitly teach microarray and the density of the microplates for screening samples. MacBeath et al. teach a microarray having microwell density of 2000 spots per  $\text{cm}^2$ . (See Figure 4) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of covalently attaching linkers both to microplates and capturing antibody of Bosslet et al. with the microarray and its density as taught by MacBeath et al., since the mass screening is the ultimate purpose in microarray and the density of the array involves only skill in the art.

#### ***Response to Applicant's Arguments***

8. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.
9. The rejections of claims 1, 3, 4, 7, 9 and 10 under 35 U.S.C. 102 (a) as being anticipated by MacBeath et al. is withdrawn.
10. The rejections of claims 2, 5, 6, and 8 under 35 U.S.C. 103(a) as being unpatentable over MacBeath et al. in view of Wagner et al. is withdrawn.

#### ***Conclusion***

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-9434.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu

Examiner

Art Unit 1641

November 20, 2003



**LONG V. LE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

11/28/03